In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-1821V

FELICIA INEZ WILLIAMS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: March 3, 2023 Special Processing Unit (SPU); Ruling on Motion to Dismiss; Factual Ruling, Pneumovax 23 Vaccine; Tetanus Diphtheria acellular Pertussis (Tdap) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Samuel A. Dion, Dion & Goldberger, Philadelphia, PA, for Petitioner.

Naseem Kourosh, U.S. Department of Justice, Washington, D.C., for Respondent.

ORDER DENYING MOTION TO DISMISS, AND
FACT RULING REGARDING DISPUTED VACCINATION ISSUES[1]

On December 11, 2020, Felicia Inez Williams filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et. seq, (the "Vaccine Act" or "Program"). Petitioner alleged that she suffered a right-sided shoulder injury related to vaccine administration ("SIRVA") following receipt of a pneumococcal vaccine in her right arm. ECF No. 1 ("Original Petition"). The case was assigned to the Special Processing Unit of the Office of Special Masters.

After a review of the Original Petition and supporting documents, Respondent filed a Motion to Dismiss, asserting that Petitioner had failed to satisfy a threshold statutory requirement for compensation, namely that she had not proven that she suffered an injury

[1] Because this unpublished Order contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

caused by a vaccine covered by the Vaccine Program. Respondent's Status Report and Motion to Dismiss ("Mot."); ECF No. 32. For the reasons discussed herein, Respondent's motion is **DENIED**. I also find that there is preponderant evidence to establish that Petitioner received the covered tetanus vaccine to her right shoulder as the amended pleadings allege.

I. Relevant Procedural History

On December 11, 2020, Ms. Williams filed her Original Petition and 17 exhibits alleging that she suffered a shoulder injury related to vaccination ("SIRVA") as a result of a pneumococcal conjugate vaccine she received on March 13, 2019. ECF No. 1. The petition alleges that Petitioner received a tetanus vaccine to her left arm and a pneumococcal conjugate vaccine to her right arm on March 13, 2019, at a Rite Aid Pharmacy located in Philadelphia, PA. Original Petition at 1-2.

On July 23, 2021, the initial status conference was held. During the status conference, Petitioner's counsel was informed that the pneumococcal vaccine that Petitioner received was not the pneumococcal conjugate vaccine as the petition alleged, but rather the pneumococcal polysaccharide vaccine ("Pneumovax 23") as confirmed by the vaccination record. ECF No. 23 (Scheduling Order); Petitioner's Exhibit ("Ex.") 2 at 3; Ex. 2(a) at 2. The only type of pneumococcal vaccine listed on the Vaccine Injury Table is a pneumococcal conjugate vaccine. 42 C.F.R. § 100.3(a)(XII). Pneumovax 23 is not covered by the Program. *See, e.g.*, *Bundy v. Sec'y of Health & Human Servs.*, No. 12-769V, 2014 WL 348852, at *2 (Fed. Cl. Spec. Mstr. Jan.8, 2014); *Morrison v. Sec'y of Health & Human Servs.*, No. 04-1683V, 2005 WL 2008245, at *2 (Fed. Cl. Spec. Mstr. July 26, 2005).

Following the status conference, I issued an order directing Petitioner to file a status report indicating how she would like to proceed – either by filing an amended petition and supporting documentation demonstrating that she was injured by a covered vaccine or by filing a pleading to exit the Vaccine Program. *Id.* at 2.

On August 18, 2021, Petitioner filed an Amended Petition, an Amended declaration, and an Amended Pre-Assignment Review Questionnaire. ECF Nos. 27, 29. Like the Original Petition, the amended petition alleged that Petitioner sustained a SIRVA in her right arm. ECF No. 27 Amended Petition at 1-2, 14. However, with respect to the vaccine at issue, the Amended Petition alleged the opposite of the Original Petition: i.e., that Petitioner had received the *tetanus* vaccine in her right arm and the uncovered *pneumococcal* vaccine in her left arm, and that her right-sided SIRVA was due to the tetanus vaccine. *Id. (emphasis added).* Similarly, Petitioner's Amended Declaration stated that she received the tetanus vaccine in her right arm and the pneumococcal

vaccine in her left arm. Ex. 3(a) at 2-3. She stated: "I had mistakenly signed a declaration on December 3, 2020, attesting that the pneumonia vaccine was injected into my right arm, but this was a mistake." *Id*. at 3.

On September 21, 2021, I held a recorded status conference with Petitioner's counsel and Respondent's counsel, at Respondent's counsel's request. ECF No. 31 at 1. Respondent's counsel voiced her concerns regarding the procedural history of the case, arguing that there was a material change in Petitioner's allegations regarding the vaccines and site of administration in this case. *Id.* at 1. I acknowledged Respondent's concerns but stated that, absent a showing otherwise, the site of administration of the vaccines in question would be considered a factual issue, which would be decided on the basis of the record. *Id.* I directed Respondent to file an initial informal assessment or other appropriate pleading, carefully reviewing the record and setting forth evidence for me to consider. *Id.* at 1-2.

On November 12, 2021, Respondent filed a status report and Motion to Dismiss. ECF No. 32 ("Mot."). Respondent argued that Petitioner had failed to demonstrate that she received a vaccine that is set forth in the Vaccine Injury Table. 42 U.S.C. § 300aa-11(c)(1)(A); Mot. at 8. Respondent maintained that the relevant evidence preponderantly showed – based on both the quantity and relative strength of the medical records – that, to the extent that Petitioner received a vaccine in her right arm on March 13, 2019, it was a pneumococcal polysaccharide vaccine, i.e., the Pneumovax 23 vaccine, which is not covered by the Vaccine Program. *Id*. at 9-13. Respondent also maintained that Petitioner had offered no new evidence and no explanation for how she had discovered, immediately after the initial status conference, that she had initially made a "mistake" in her allegations regarding which vaccine caused her SIRVA. Mot. at 2-3, 12. Respondent also argued that the great weight of the evidence – as demonstrated by both the quantity and relative strength of the contemporaneous medical records and Petitioner's own expert report – established that, if any vaccine was administered in Petitioner's right arm on March 13, 2019, it was the Pneumovax 23 vaccine, which is not covered in the Program. Mot. at 11-12.

On January 18, 2022, Petitioner filed a Second Amended Petition and Second Amended Declaration. ECF No. 34 ("Second Amended Petition"); Ex. 3. Also on January 18, 2022, Petitioner filed a response to Respondent's Motion. ECF No. 35 ("Response"). In her Response, Petitioner argued that while reviewing the medical records with her counsel after the July 2021 status conference, she "realized that she had erroneously believed that the pneumonia vaccine was administered to her right arm, and, in fact, it was the tetanus vaccine that was administered to her right arm." Response at 1-2. Petitioner also argued that she must have received the tetanus vaccine to her right arm as her vaccination record indicates that the pneumococcal vaccine was administered

subcutaneously while the tetanus vaccine was administered intramuscularly. *Id*. In support of this argument, she states that the Centers for Disease Control and Prevention ("CDC") recommends that, to the extent that PPSV23 vaccines are administered intramuscularly, they be administered in the opposite arm from tetanus vaccines. Response at 2-3 (citing Exs. 19, 21); *id.* at 9. From this premise, she argues that, because "it was not impossible for Rite Aid to follow the CDC recommendation," "something was injected into petitioner's right arm." *Id.* at 4. She then concludes that, because she "suffered SIRVA to her right arm, which could only be caused by incorrect administration of an intramuscular injection, the weight of the evidence indicates that the intramuscular administration of the tetanus vaccine was the cause of petitioner's right arm injury." *Id.* at 4; *see also id.* at 5.

On February 22, 2022, Respondent filed a Reply to Petitioner's Response ("Reply") arguing that Petitioner's Response had not cured her failure to satisfy a threshold statutory requirement for compensation, namely that a covered vaccine caused her injury. *See* ECF No. 37.

II. Medical History

On March 13, 2019, Ms. Williams received a Tdap vaccine and a Pneumovax 23 vaccines at Rite Aid pharmacy. Ex. 2 at 2; Ex. 2(a) at 4-5. Her medical history does not contain any indication of prior right shoulder symptoms. *See generally*, Ex. 5.

The vaccination record states that she received both vaccines in her left upper arm. Of note, for the Tdap vaccine the "Site of Admin/Rout of Admin" is listed as "intramuscular," while the Pneumovax vaccine is listed as "Injection." *Id.* In her Original Petition and declaration, Petitioner stated that the pharmacy records are incorrect as to the site of administration for the pneumococcal vaccine, as she actually received that vaccine in her right upper arm. Original Petition at 2 at n.1; Ex. 3 at 1-2.

Several hours later on March 13, 2019, the same day of the vaccinations, Petitioner presented to the emergency department ("ED") at Albert Einstein Medical Center, reporting that she had received tetanus and pneumococcal vaccines earlier in the day, and that she was experiencing right-sided chest, arm, and neck, pain, as well as dry mouth and tingling in the fingers. Ex. 4 at 3-4, 7. An addendum added later that day to the record stated:

> 52yoF . . . presenting with right sided chest pain, arm pain and neck pain. Symptoms started approximately 4hrs pta… Pt got tetanus shot and pneumo shot at 2pm today and symptoms started 2 hrs later. Pt initially

> thought she was having an allergic reaction but does not have itching swelling or pain over the injection shot. She has gotten tetanus shot in the past without having a reaction.

Ex. 4 at 7. Ms. Williams underwent an EKG which showed tachycardia. *Id*. Additional lab work was ordered. *Id*. She was discharged the same day. *Id*.

On April 2, 2019, Ms. Williams presented to her primary care provided ("PCP"), Steven Schmidt, D.O. (family medicine), to whom she reported that she was experiencing minor right deltoid and upper arm pain following a vaccination two weeks prior. Ex. 6 at 1. Petitioner was noted to have passive movement of the right arm, and pain with active movement. *Id*. She was referred to a physical therapist for further assessment of her right shoulder. *Id*. at 5.

On April 5, 2019, Ms. Williams presented to the ED at Chestnut Hill Hospital complaining of "R[ight] arm pain and R[ight] shoulder pain after receiving a tetanus shot in R[ight] arm approximately 3 weeks ago. Reports pain as throbbing to bicep. Pt reports pain worsens w/movement. Took naproxen without relief." Ex 7 at 3, 6. The report from this visit further states:

> [P]t is a 52 year old female … who presents to the emergency room for eval of right sided shoulder pain x 3 weeks. Pt states she got injection in both her arms three weeks ago that started this pain, right worse then left … Pt states the left arm resolved however she is still having some pain in the right shoulder. Describes as throbby, ach[]y with some tingling in the fingers. Worse with movement…"

Ex. 7 at 3. Ms. Williams underwent an X-ray of the right shoulder scapula and upper arm with normal findings. Ex. 7 at 16-17. She was assessed with muscular arm pain and prescribed Toradol and Flexeril. She was instructed to follow up with her primary care provider. *Id*. at 5.

On April 15, 2019, Ms. Williams returned to Dr. Schmidt reporting that she had presented to the Einstein ED on March 13, 2019, due to excruciating right shoulder pain that developed hours after receiving a pneumococcal vaccination in her right arm that day. Ex. 6 at 6. She reported that "within hours of getting the vaccination she had a reaction to it where she could not lift her arm up, numbness in fingers." *Id*. Ms. Williams reported that even with taking Motrin and Flexeril, there had been no improvement in her symptoms. *Id*. She described the pain as a "dull, toothache pain." *Id*. Dr. Schmidt noted

tenderness to the right deltoid, and limited range of motion during the internal and external rotation of the deltoid secondary to pain." *Id*. at 7. Dr. Schmidt ordered an EMG. *Id*.

On April 24, 2019, Ms. Williams presented to neurologist, Tim Lachman, M.D. for an evaluation of her right arm pain. Ex. 8 at 4. Dr. Lachman noted that Petitioner "has intractable right upper arm pain since March 13, 2019. On that day she was vaccinated for pneumonia in her right deltoid. Two hours later she could not move her fingers or arm…" *Id*. On examination, Dr. Lachman noted good arm strength, but Petitioner could not abduct or forward flex her right arm above horizontal. *Id*. An EMG study yielded normal results. *Id*. at 4-7.

On April 29, 2019, Ms. Williams returned to Dr. Schmidt for a refill on her medications. Ex. 6 at 9. She reported that she still had ongoing right shoulder pain after receiving immunizations in March. *Id*. Ms. Williams stated that she had seen a neurologist and undergone an EMG, but her results were within normal limits. *Id*. She stated that her neurologist was not sure what was causing her right shoulder pain. *Id*.

On May 29, 2019, Petitioner returned to Dr. Schmidt for "chronic care management and right shoulder pain." Ex. 6 at 15. Ms. Williams reported that she continued to experience right shoulder pain "after getting pneumonia vaccination in the right arm in March 2019." *Id*. She stated that while Flexeril and Motrin were helping, she was still experiencing a constant throbbing in her shoulder. *Id*. On examination, Dr. Schmidt noted limited range of motion of the right shoulder "with tenderness to palpation over the biceps and biceps tendon." *Id*. at 16. The plan of care included a referral to physical therapy to work on improving Petitioner's range of motion and a continuation of Flexeril and NSAIDs. *Id*.

On June 11, 2019, Ms. Williams presented for an initial physical therapy ("PT") evaluation at Progress PT, reporting "right shoulder pain since March, she noted that when she was injected with a vaccine (pneumonia and tetanus – reports she was given a tetanus shot prior) …" Ex. 8 at 12. She was noted to have signs of adhesive capsulitis. *Id*. at 14. It was recommended that she attend physical therapy twice weekly for six weeks. *Id*. at 15.

On July 1, 2019, Ms. Williams presented to Dr. Schmidt in follow up for chronic care management. Ex. 6 at 18. The notes from this visit carried over the previous history recounted by Ms. Williams where she reported right shoulder pain since March 2019 following a pneumonia vaccination. *Id*. Ms. Williams stated that she had been attending physical therapy two to three times a week but wanted to be evaluated by an orthopedist.

Id. Dr. Schmidt prescribed a Lidoderm patch to Ms. Williams and provided her with a referral to an orthopedist. *Id*. at 22.

On July 15, 2019, Ms. Williams presented to the ED at Temple University Hospital, stating "received tetanus and pneumonia shot in R arm 5 months ago and has had pain since. Reports initial pain started same day as vaccines given, was seen at ED and Rx pain control. States has had pain in R upper arm since…" Ex. 10 at 8. On examination, there was no swelling, but her right shoulder was tender to palpation. *Id*. at 9. She had limited range of motion and was unable to lift her right arm overhead. *Id*. The attending physician noted that Petitioner would need further evaluation as an outpatient. *Id*. at 10. Ms. Williams's pain had improved at the time of discharged and she was prescribed Naproxen. She was instructed to follow up with her primary care physician. *Id*.

On July 29, 2019, Ms. Williams presented to orthopedist Vishal Saxena, M.D. for an initial evaluation of right shoulder pain and arm pain. Ex. 11 at 4. Dr. Saxena's notes state,

> Her symptoms started on 3/10/19 when she received the Pneumovax vaccine to her right deltoid. Almost immediately afterwards, she noted pain in her right arm along with difficulty breathing and was rushed to the emergency department to rule out a cardiac event … Since then, she has noted near constant right shoulder and upper extremity pain that goes from her neck all the way down to her fingers…

Ex. 11 at 4. On physical examination, Dr. Saxena's noted limited range of motion of the right deltoid and as unable to assess impingement tests due to pain. *Id*. at 6. The impression was "right upper extremity pain, adhesive capsulitis versus injection-related subdeltoid bursitis." *Id.* at 7. Dr. Saxena also noted "[s]he may have had a vaccine related subdeltoid bursitis which caused significant shoulder pain that has now progressed to adhesive capsulitis." *Id*. Ms. Williams underwent X-rays of her right shoulder and cervical spine which were all within normal limits. Ex. 11 at 32-44.

On July 31, 2019, Ms. Williams followed up with Dr. Schmidt for her right shoulder pain. Ex. 6 at 24. She reported that she had been going to physical therapy, but that her pain was worse afterwards. *Id*. Ms. Williams stated that she had been seen by the orthopedist who had "concerns for frozen shoulder v vaccine related injury to shoulder." *Id*. She was awaiting an evaluation for arthroscopic exploration. *Id*. On examination, Ms. Williams exhibited decreased active and passive range of motion in all directions of the right shoulder, tenderness to palpation of the lateral and posterior deltoid, and decreased

strength (4/5) in the right hand as compared to the left. *Id*. at 26. She was instructed to continue taking Naproxen and Gabapentin was added. *Id*. at 27.

Also on July 31, 2019, Petitioner was discharged from physical therapy after attending a total of five sessions. Ex. 9 at 1. The notes from the discharge stated that "[p]atient notified front desk is pending surgery on her right shoulder and to hold physical therapy until after her surgery on the 22nd." *Id*.

On August 28, 2019, Ms. Williams followed up with Dr. Schmidt who noted continued right shoulder pain since receiving a pneumococcal vaccination in March 2019. Ex. 6 at 28. Dr. Schmidt noted that Ms. Williams had received a steroid injection in her right shoulder but experienced no improvement. *Id*. She had discontinued physical therapy due to pain but was scheduled to see a shoulder specialist in New York. *Id*. On examination, Dr. Schmidt noted "severely limited shoulder abduction and internal/external rotation. Pt admits to not being able to put on her own bra. Radial and brachial pulses present." *Id*. Ms. Williams was scheduled for her next steroid injection the next month. *Id*. at 32.

On September 6, 2019, Ms. William presented to orthopedist Eric Strauss, M.D. reporting that she

> received tetanus and pneumovax vaccinations at Rite Aid in March 2019. Immediately following the injection she developed severe right shoulder pain. Her pain was severe enough to prompt a visit to a local ED where xrays were taken which were negative… Ms. Williams has continued to experience right shoulder pain, limitation of her ROM and pain associated with weakness… A few weeks ago Ms. Williams received a subacromial corticosteroid injection which did not impact her symptoms at all. Ms. Williams believes she has SIRVA. She presents to our office for evaluation and treatment.

Ex. 12 at 1. On examination, Ms. Williams was noted to "show[] evidence of deformity, atrophy or asymmetry." *Id*. at 2. She was noted to tenderness to palpation and limited range of motion. *Id*. She also demonstrated decreased strength and positive signs on the Hawkin's, Speed's and Yergason's impingement tests. *Id*. at 3. Dr. Strauss stated that he did not believe Petitioner had SIRVA but believed an MRI of her rotator cuff was necessary. *Id*.

On September 19, 2019, Ms. Williams underwent an MRI of her right shoulder. Ex. 13 at 1. The impression noted rotator cuff tendinosis/tendinopathy, degenerative superior labrum without tear, AC joint arthritis, but there was no evidence of rotator cuff tear. *Id*.

On September 26 and November 25, 2019, Ms. Williams saw Dr. Schmidt in follow-up for various issues, including right shoulder pain, but did not describe its origin in her reporting. Ex. 6 at 33, 38.

On January 6, 2020, Petitioner returned to Dr. Schmidt for chronic care management. Ex. 6 at 41. Dr. Schmidt notes in error that Ms. Williams "experienced a muscle reaction after receiving the flu[*sic*] vaccine which has caused her severe R arm pain … Pt also has trouble sleeping due to her arm… Pt overall feels well aside from her arm pain . . ." Ex. 6 at 41.

On January 10, 2020, Ms. Williams presented to Sean Cleymaet, M.D., a neurologist for an initial evaluation of her right arm pain. Ex. 14 at 67. She reported that she "received a pneumovax vaccine at Rite Aid in early March 2019 and that several hours afterward she developed an acute burning pain in the area of the injection site … She said the pain was very severe and spread to her entire upper arm although it was most severe over her lateral upper arm… Since that time her pain has been chronic, described as a deep aching, most severe over the site of the prior injection, worsened with movement, and over time she became unable to lift her arm above the shoulder." *Id*. Dr. Cleymaet's assessment was that her pain was unlikely to be neurologic in nature. *Id*. He noted that there were elements of complex regional pain syndrome, but Ms. Williams's presentation was not a "perfect fit" for that diagnosis either. *Id*. He ordered a follow up MRI and a referral to pain management. *Id*. at 69.

On February 3, 2020, Ms. Williams saw Dr. Schmidt in follow up for chronic care management. Ex. 6 at 45. She continued to complain of right upper extremity pain and limited range of motion secondary to injection site reaction. *Id*. Ms. Williams reported that she was being followed by neurology, an orthopedist, and pain management, and she had an MRI scheduled for February 10, 2020, for a reevaluation. *Id*. The assessment included a diagnosis of "complex regional pain syndrome of R upper limb." *Id*. at 48.

On February 10, 2020, Ms. Williams underwent an MRI of the right humerus which showed a "small amount of fluid in the subacromial subdeltoid bursa which may represent bursitis." Ex. 14 at 82; Ex. 15 at 4. The MRI was otherwise normal.

On February 25, 2020, petitioner saw Lorretta Brown, D.O. (family medicine). Ex. 16 at 2. The record of this visit is brief, handwritten, and extremely difficult to read, but

there is a notation of "onset" on March 13, 2019, and a mention of rotator cuff tendonitis or tendinosis of the right shoulder, presumably indicating that Ms. Williams reported right shoulder symptoms beginning on March 13, 2019. *Id.*

On February 28, 2020, Ms. Williams returned to Dr. Cleymaet to review the results of her recent MRI. Ex. at 14 at 27. The history of present illness was copied from the previous appointment and states that Ms. Williams reported receiving the Pneumovax to her right arm in March 2019. *Id*. After reviewing the MRI, Dr. Cleymaet noted that there was a small amount of fluid in the subacromial subdeltoid bursa which may represent bursitis. *Id.* at 30. He noted that from a neurological perspective, there was no further management or workup indicated that time. *Id*. He indicated that Petitioner was seeing pain management and was hopeful they would be able to help with the persistent pain. *Id*.

On March 10, 2020, Ms. Williams returned to Dr. Schmidt noting ongoing, chronic right shoulder pain. Ex. 6 at 49. She reported that her MRI had shown small amounts of fluid in her subacromial, subdeltoid bursa "which may represent bursitis." *Id*. Petitioner was now taking Oxycodone by pain management and was considering a procedure to drain the fluid from her bursa. She was also considering "low intensity therapy" as suggested by her orthopedist. *Id*. Dr. Schmidt instructed her to continue following up with her orthopedist and pain management team. *Id*. at 51.

On July 6, 2020, Ms. Williams returned to Dr. Schmidt, reporting arthritic pain in her shoulders and knees. Ex. 6 at 53.

On July 7, 2020, Ms. Williams presented to Gaurav Trehan, M.D., at Temple Faculty Physicians – Pain Management, who prepared an evaluation and assessment of Ms. Williams's right arm pain. Ex. 6 at 58. Dr. Trehan noted that Ms. Williams reported a "history of a pneumonia and tetanus vaccine on 3/13/2018[*sic*] at a Rite Aid pharmacy. 3 hours after the vaccination she reported severe pain in the right arm and had to be taken to the emergency room." *Id.* Dr. Trehan noted that Ms. Williams underwent physical therapy and received a steroid injection to her right deltoid which did not relieve her pain. *Id*. He noted that Ms. Williams underwent an MRI of the right humerus on January 10, 2020, which showed a small amount of fluid in the subacromial subdeltoid bursitis which may represent bursitis. *Id*. at 59. She had also undergone an MRI of the cervical spine on December 3, 2019, which showed "multilevel early spondylitis changes in the cervical spine, without spinal canal stenosis or neuroforaminal narrowing. *Id*. at 60. The EMG studies were within normal limits. *Id*. On physical examination of the right shoulder, Ms. Williams showed decreased range of motion, tenderness, and pain, although she exhibited normal strength. *Id*. Dr. Trehan assessed Ms. Williams with "chronic right arm pain secondary to Shoulder Injury Related to Vaccine Administration (SIRVA)." *Id*. at 62.

Dr. Trehan discussed discontinuing opioid therapy given Ms. Williams's history of bipolar disorder. *Id*. The recommendations from this evaluation included starting diclofenac ointment to the right arm, possible lidocaine ointment in the future of diclofenac was unsuccessful, Cymbalta, and cognitive behavioral therapy and mindfulness therapy. *Id*.

On October 21, 2020, Ms. Williams presented to orthopedist Eric Bontempo, M.D., for an orthopedic consultation. Ex. 17 at 1. Dr. Bontempo had a "long discussion" with Ms. Williams and her husband, took a history, performed a physical exam, and reviewed her prior medical records. Ex. 17 at 4. Petitioner reported to Dr. Bontempo the following:

> She is a 53-year-old right-hand dominant female who presents with a complaint of right shoulder pain. She said it all started after she received a pneumonia vaccine into her right shoulder on 3/13/2019. She said she went to a pharmacy and was given the pneumonia vaccine in her right shoulder and a tetanus shot in her left shoulder. She was not sure why she got the tetanus shot. The shot itself did cause pain, but she went home and within 2 hours started to develop severe pain in her right shoulder and upper arm. She said the pain was so bad that she started having a panic attack and was having trouble breathing… She denies having any prior injuries or problems to her right shoulder or arm. She has never had any treatment to this area in the past. She also said that she has had flu and pneumonia shots in her arm before and has never had any problems with them.

Id. at 1. Upon examination, Ms. Williams "was observed be visibly uncomfortable." *Id*. An examination of the right shoulder revealed some generalized warmth as compared with the opposite shoulder. *Id*. at 2. Dr. Bontempo noted that there "was marked tenderness over the anterior and lateral subdeltoid and deltoid region of her right shoulder. There was also significant tenderness of the lateral aspect of the humerus and distal deltoid at its insertion site. The majority of the tenderness was in her lateral deltoid area…"

Dr. Bontempo had reviewed Petitioner's previous medical records and his assessment stated

> it is my opinion within a reasonable degree of medical certainty that Ms. Williams has sustained an injury to her right shoulder as a result of the pneumonia vaccine, resulting in subacromial/subdeltoid bursitis that result in severe pain in her right shoulder causing a frozen shoulder/adhesive capsulitis. I also believe there is a component of chronic regional pain syndrome as a direct result of this injury to her shoulder. Given the fact that she has never had any problems with her right shoulder in the past and

> there is no evidence of any cervical disc disease, neurologic condition or pre-existing problems in her right shoulder, this condition is consistent with shoulder injury related to vaccine administration (SIRVA).

Ex. 17 at 5. Dr. Bontempo recommended arthroscopic surgery along with manipulation of Petitioner's shoulder under anesthesia. *Id*. No additional records have been filed.

III. Affidavit Testimony Regarding Vaccination

In her initial affidavit, Ms. Williams averred that she received a tetanus vaccine in her *left* arm, and a pneumococcal conjugate vaccine in her right arm at Rite Aid Pharmacy. Ex. 3 at 1. She further averred that hours later, she felt severe pain in her *right* shoulder (where the pneumococcal vaccine was purportedly administered). *Id*. at 2.

In her second affidavit, Ms. Williams averred that she actually received a tetanus vaccine in her *right* arm and a pneumonia vaccine in her left arm at Rite Aid pharmacy. Ex. 3(a) at 1. The remainder of the declaration is identical to the first affidavit with the exception of the identification of the vaccinations. As an explanation for this error, Petitioner has alleged that she "had erroneously believed that the pneumonia vaccine was administered to her right arm, and, in fact, it was the tetanus vaccine that was administered to her right arm." Response at 2-3.

IV. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which

are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). However, the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum*. *Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

V. Ruling Regarding Fact and Site of Vaccine Administration

It is generally recognized in the Program that where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie,* 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, as in this case, when "written records which are, themselves, inconsistent," they "should be accorded less deference than those which are internally consistent." *Lowrie*, at *19. There is no doubt that the medical records are themselves inconsistent, and thus should be accorded less

deference than those which are internally consistent. The issue is that there are very few records that are even internally consistent, making it difficult to resolve the issue at hand.

The two relevant facts that are not in dispute are: (1) Petitioner received both the Pneumovax 23 vaccine (uncovered) and tetanus (covered) vaccines on March 13, 2019, at Rite Aid Pharmacy, and (2) Petitioner did not have a history of right shoulder symptoms prior to March 13, 2019. The factual questions that must be resolved are which vaccines Ms. Williams received to each arm, or whether she received both vaccines to one arm – and if so, which arm.

The circumstances are further muddled because of the inconsistent reporting provided by Ms. Williams each time she saw a medical provider for her shoulder pain. Based on my overall records review, however, this appears to be because Ms. Williams is simply a poor historian and was unable to accurately recall which vaccine(s) she received to each arm on March 13, 2019, rather than a purposeful mischaracterization of the facts. Thus, an evaluation of the facts as a whole, in addition to reviewing the most contemporaneous medical records, is important.

In his Motion, Respondent summarizes the medical records based on the reporting of situs by Ms. Williams and reports that there were:

- **Three occasions** where Ms. Williams reported shoulder pain without mention of onset or vaccinations. Mot. at 9.
- **Three occasions** where Ms. Williams mentioned both the pneumococcal and tetanus vaccines but did not specify which vaccines were administered to each arm. Mot. at 10.
- **One occasion** where Ms. Williams mentioned receiving both vaccines to her right arm. Mot. at 10.
- **One occasion** where Ms. Williams mentioned receiving the tetanus vaccine her right arm. Mot. at 11.
- **Five occasions** where Ms. Williams mentioned receipt of vaccination in her right arm on March 13, 201, but did not specify what type of vaccine. Mot. at 9, and
- **Ten occasions** where Ms. Williams reported receiving a pneumococcal vaccine in her right arm on March 13, 2019.

Upon review of these citations, I will note that of the ten occasions where Ms. William reported receiving the pneumococcal vaccine to her right shoulder, four occurred at visits with Dr. Schmidt, who appears to have carried over the reporting of situs from prior visits. It is also unclear from each of these citations whether Ms. Williams specifically reported to the medical provider that she received the pneumococcal vaccine to her right

arm, or whether this statement was taken from other medical records. There is simply no way to confirm whether Ms. Williams specifically reported the situs in each of these visits. The only thing that is clear is that Ms. Williams was a poor historian was extremely inconsistent with her reporting of situs to each of her medical providers.

Given these circumstances, the fairest approach to resolving this fact dispute is to give considerably less weight to Ms. Williams's reporting of situs to a medical provider in each instance, and instead to place more emphasis on the most contemporaneous medical records and what objective facts they highlight. I also will not give substantial credence to Ms. Williams's later created pleadings and testimony, which changed all of her claims of receiving the pneumococcal vaccine to right shoulder, to instead, receiving the covered tetanus vaccine to her right shoulder. These changes came only after Ms. Williams was made aware that the pneumococcal vaccine she received was not a covered vaccine. It is troubling and difficult to understand how Ms. Williams could have suddenly recalled with specificity which vaccine she received to each arm, with the only change in her knowledge being that the pneumococcal vaccine was uncovered. (This change in her testimony overall substantially hurts her credibility in this case, as her change in recollection clearly would benefit her chances of recovery, and will be taken into account in other regards, as discussed below).

The original Rite Aid vaccination record itself states that Ms. Williams received *both* the tetanus and Pneumovax 23 vaccines in her *left* arm March 13, 2019. Ex. 2 at 2: Ex. 2(a) at 4-5. This appears to be in clear error - as all the medical records following vaccination consistently report (if nothing else) that Ms. Williams received *at least one vaccine* in her right deltoid that date. This fact is also evidenced by Ms. Williams's consistent reporting of receiving at least one vaccination to her right deltoid and the subsequent presentation of a right shoulder injury immediately following vaccination, where no injury previously existed. Ex. 4 at 3-7. Thus, there is a least one error in the medical records regarding the situs of the March 13, 2019 vaccinations.

A closer look at the vaccination record shows that for the Tdap vaccine the "Site of Admin/Rout of Admin" is listed as "intramuscular," while the Pneumovax vaccine is listed as "Injection." *Id.* While not definitive, this notation insinuates that the pneumococcal vaccine may have been administered in some alternative fashion – such as subcutaneously under the skin. As Petitioner notes in her Response, while the Pneumovax 23 vaccine can be administered both intramuscularly and subcutaneously, the CDC *recommends* that it be administered subcutaneously. Response at 3 (*citing* Exhibit C). This recommendation alone would not be significant enough to prove that Pneumovax 23 vaccine was actually administered subcutaneously to Ms. Williams. However, coupled with the fact that the tetanus vaccine was clearly identified as being

administered "intramuscularly," this lends additional support to the proposition that the Pneumovax 23 vaccine was, in fact, administered to Petitioner subcutaneously. This is a significant factor, as SIRVA is defined by the Vaccine Act as a shoulder injury cause by injection of an intramuscular vaccine.

The next significant medical records are the most contemporaneous medical records following the March 13, 2019, vaccinations. Several hours after receiving the vaccinations, Ms. Williams presented to the emergency room reporting right-sided chest, arm, and neck pain. Ex. 4 at 3-4, 7. While the medical records from this visit did not specifically identify which vaccines were administered to Ms. Williams's deltoids, it does identify that Ms. Williams received both vaccines and specifically identifies one vaccine, the tetanus vaccine, as being one that had caused no reactions in the past. Ex. 4 at 7 ("Pt got tetanus shot and pneumo shot at 2pm today and symptoms started 2 hrs later. . . . She has gotten tetanus shot in the past without having a reaction"). While not dispositive, this record indicates that Ms. Williams believed at one point, very contemporaneously with the precipitating event, that the tetanus vaccine may have the cause of her right-sided chest and arm symptoms.

The next most contemporaneous medical record is dated April 2, 2019, approximately two weeks after vaccination, where Ms. Williams presented to her PCP, Dr. Schmidt. Here, Petitioner simply reports right upper arm and deltoid pain following vaccinations. Ex. 6 at 1. This record does not identify the specific situs for either vaccine.

Three days later, on April 5, 2019, Ms. Williams went to the emergency department at Chestnut Hill Hospital complaining of "R[ight] arm pain and R[ight] shoulder pain after receiving a tetanus shot in R[ight] arm approximately 3 weeks ago. Reports pain as throbbing to bicep. Pt reports pain worsens w/movement. Took naproxen without relief." Ex 7 at 3, 6. The record further states:

> [P]t is a 52 year old female … who presents to the emergency room for eval of right sided shoulder pain x 3 weeks. Pt states she got injection in both her arms three weeks ago that started this pain, right worse then left … Pt states the left arm resolved however she is still having some pain in the right shoulder. Describes as throbby, ach[]y with some tingling in the fingers. Worse with movement…"

Ex. 7 at 3. This record is the first most contemporaneous medical record where Ms. Williams identifies the situs of vaccination. From this record, Ms. Williams reported that she received the tetanus vaccine in her *right* shoulder, and that she received another vaccine in her left shoulder, which caused her some pain but had since resolved. *Id*.

However, the next medical record, which is dated ten days later, on April 15, 2019, Ms. Williams reports to her PCP, Dr. Schmidt, that she instead received the Pneumovax vaccine to her right shoulder. Ex. 6 at 6. From this date forward, the reporting of situs becomes far more inconsistent and unreliable.

Overall, this set of especially contemporary medical records demonstrate that Ms. Williams clearly had ***some*** injury to her right shoulder following vaccination which was not present before. Just two weeks after vaccination, Ms. Williams was noted to have passive movement of the right arm and shoulder, and pain with active movement. Ex. 6 at 1-2. Her PCP, Dr. Schmidt, noted on examination that Ms. Williams had tenderness to the right deltoid and limited range of motion during the internal and external rotation of the deltoid secondary to pain. Ex. 6 at 7. Petitioner's neurologist, Dr. Lachman, noted good right arm strength during his examination, but Ms. Williams could not abduct or forward flex her right arm above horizontal. Ex. 8 at 4-7. During an initial physical therapy evaluation, Ms. Williams was noted to have signs of adhesive capsulitis. Ex. 8 at 14. Dr. Saxenda, an orthopedist, noted his impression that Petitioner had adhesive capsulitis versus injection related subdeltoid bursitis. Ex. 11 at 4-6. Orthopedist, Dr. Eric Strauss, noted that Ms. Williams demonstrated "evidence of deformity, atrophy or asymmetry" as well as tenderness to palpation and limited range of motion of the right shoulder. Ex. 12 at 1-2. Ms. Williams's right shoulder symptoms were positive on shoulder impingement tests, i.e., Hawkins, Speeds, and Yergasons. Ex. 12 at 3. An MRI of her right shoulder showed evidence of rotator cuff tendinosis/tendinopathy, degenerative superior labrum without tear, and AC joint arthritis. Ex. 13 at 1. A second MRI demonstrated a "small amount of fluid in the subacromial subdeltoid bursa which may represent bursitis", Ex. 14 at 82, a finding often seen in SIRVA cases. This evidence also weighs in favor of an intramuscular vaccine as associated, since a subcutaneously-administered vaccine is unlikely to cause such an injury.

Weighing the foregoing, I find that the evidence preponderates, *barely*, in favor of a finding that the tetanus vaccine, which was clearly identified as being administered intramuscularly, was administered to Ms. Williams's right shoulder. Ex. 7 at 3; Ex. 17 at 1-4. Likewise, given that the majority of reports that Ms. Williams gave identifying the Pneumovax vaccine as being administered to her right shoulder, coupled with the record of vaccination which indicates that both vaccines were administered in the same shoulder, I find that the evidence shows that it is more likely than not that Ms. Williams also received the Pneumovax vaccine in her right deltoid. The only objective medical record that suggests that Ms. Williams received a vaccine to her left deltoid is the vaccination record, which, as discussed above, is problematic and is likely inaccurate given that Ms. Williams did receive at least one vaccine to her right shoulder. And the evidence on manner of

administration also barely allows the conclusion that the vaccine more likely to have been administered intramuscularly was the covered vaccine – tetanus.

I am very sympathetic to Respondent's position, and frustration with the contradictory record. The change of facts in Petitioner's petitions, declarations, and statements after learning that the Pneumovax 23 vaccine was not covered by the Vaccine Act is highly concerning, and rightfully calls into question her veracity. However, an objective review and evaluation of the facts leads to a conclusion that Petitioner's revised position regarding the tetanus vaccine is more likely than not, accurate. At worst, this case represents a "close-call," and in "the Vaccine Program, petitioners are accorded the benefit of close calls." *Roberts v. Sec'y of Health & Human Servs*., No. 09-427V, 2013 WL 5314698, at *10 (Fed. Cl. Aug. 29, 2013). If Respondent chooses to maintain the position that Petitioner cannot prove which vaccine was causal, despite my determination herein, he will need to offer strong, preponderant evidence on this issue not already considered – and it is doubtful such evidence can be generated at this point.

I do strongly encourage the parties to work to informally resolve this case. And I admonish Petitioner that her transparently litigation-associated change in position to save her claim will function to limit any damages she receives on the subjective side of the damages "ledger" – in particular pain and suffering, which is inherently subjective in any case. She should only seek reimbursement of her out-of-pocket unreimbursable expenses and a *very modest recovery* for pain and suffering, given the extent to which she has harmed her credibility.

CONCLUSION

Based on the record as a whole, Petitioner has established that she more likely than not received the covered tetanus vaccine and non-covered pneumococcal vaccine to her right shoulder. Therefore, Respondent's Motion to Dismiss is DENIED.

The following is ORDERED:

(1) Petitioner shall file any updated medical records by Monday, April 17, 2023.

(2) Given my denial of the Motion to Dismiss and Findings of Fact, the parties should work to informally resolve this case, if possible. Respondent shall file a status report by Monday, May 1, 2023, with an update on the status of the parties' settlement discussions.

(3) Additional proceedings will be set after this information is filed.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master